

Office Action Summary

Application No.

10/550,907

Applicant(s)

BEN-MENACHEM ET AL.

Examiner

Sabiha Qazi

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-17 and 32-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-43 is/are allowed.
- 6) ☒ Claim(s) 11, 16, 17 and 34-37 is/are rejected.
- 7) ☒ Claim(s) 1, 2, 4-10, 12-15 and 32-33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Final Office Action

Claims 1, 2, 4-17 and 32-43 are pending. No claim is allowed.

Amendments are entered.

Summary of this Office Action dated 11/23/2008

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 112 (1) Written Description Rejection
5. 35 USC § 112 (2)-rejection
6. Response to Remarks
7. Conclusion
8. Communication

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Examiner notes that some references are cited on pages 44-48 of the specification.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 11 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply:

The process of making and the steps are missing from claim 11 (the conditions are not disclosed).

35 USC § 112 --- First Paragraph Written Description Rejection

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 17, 34-37 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Following reasons apply:

Specification discloses on page 43, the ELISA and TLC overlay assays demonstrated that antibodies were raised against the synthetic compound 19 to the same extent as native BBGL-II. Since the antibodies are very specific so it cannot be predicted for the large genus. Furthermore, Applicants have not shown that how the treatment is expected to be successful and effective by different compounds as has been claimed. Applicant is kindly requested to explain this issue.

Specification has no guidance or teaching to make and use the invention as has been claimed. For example claim 3 is drawn to compounds which are chemically synthesized. It appears that compounds of claim 1 may be isolated. Examiner could not find any isolation where compounds containing various R1, R2, L and various protein carriers of formula A had been isolated. Further the conjugates can be covalently bound to the protein carrier via the RI group. This all gives a large number of compounds and their method of use.

Similarly claims are drawn to compounds of formula A and to a method of inducing an immune response to *B. burgdorferi* in a subject, comprising administering a therapeutically effective amount of the compound of claim 1 to the subject, thereby inducing the immune response and claims are drawn to a method of preventing or treating Lyme disease in a subject, comprising administering to a subject a therapeutically effective amount of the compound of claim 1, thereby preventing or treating Lyme disease in the subject. There is no teaching or guidance in the specification for the claimed subject matter. One skilled in the art would not be able to make and use the invention.

Applicant has no possession of invention of all the claimed subject matter at the time the application was filed.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.

See *Genetech*, 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the

presence or absence of literal support in the specification for the claimed language. *See In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983).

Therefore, Applicant has no possession of the invention of the subject matter as claimed at the time of filing the application. Applicant is kindly requested to explain the issue.

See MPEP 2163.06.

The 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their

inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

Applicants claim

A compound of formula A, or a pharmaceutically acceptable salt or complex thereof, and their method of use to treat Lyme disease wherein the compounds of formula A comprises as in claim 1.

Allowable Subject Matter

Claims 38-43 are allowed. Compounds, method of use and pharmaceutically acceptable salt of the compounds presented in claim 38 is allowable. Prior art of record does not teach R2 as azide.

Claims 1, 2 and 4-10, 12-15 and 32-33 are objected for containing non elected subject matter.

Response to Remarks

Claims are amended therefore 112 (2) rejection is in-part withdrawn. Applicants may consider writing some steps and reagents to carry out the process.

Applicant may consider amending the claims when R1 represents azide. Method claims are joined for the examination.

Applicants election of group I claims 1-17 is hereby acknowledged. Applicant elect substituents L as O, however this is not the complete species. A species means complete compound where R1, R2 and L are defined with the carrier. It may be any exemplified compound disclosed in the specification.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory

period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/

Primary Examiner, Art Unit 1612

